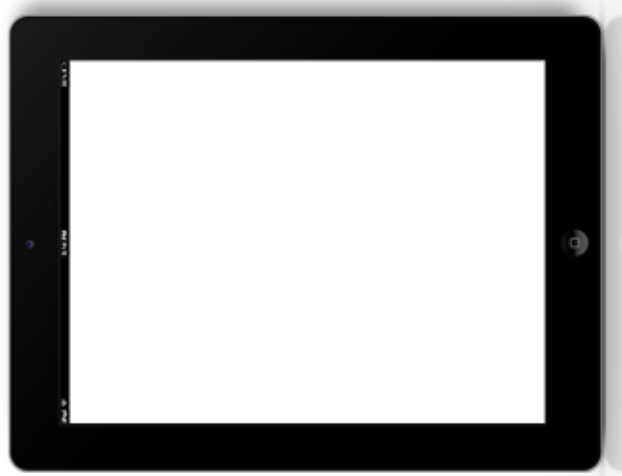
8 Operation



8.7 Control of nonconforming outputs

8.1 Operational planning and control

8.6 Release of products and services

8.2 Requirements for products and services

8.5 Production and service provision

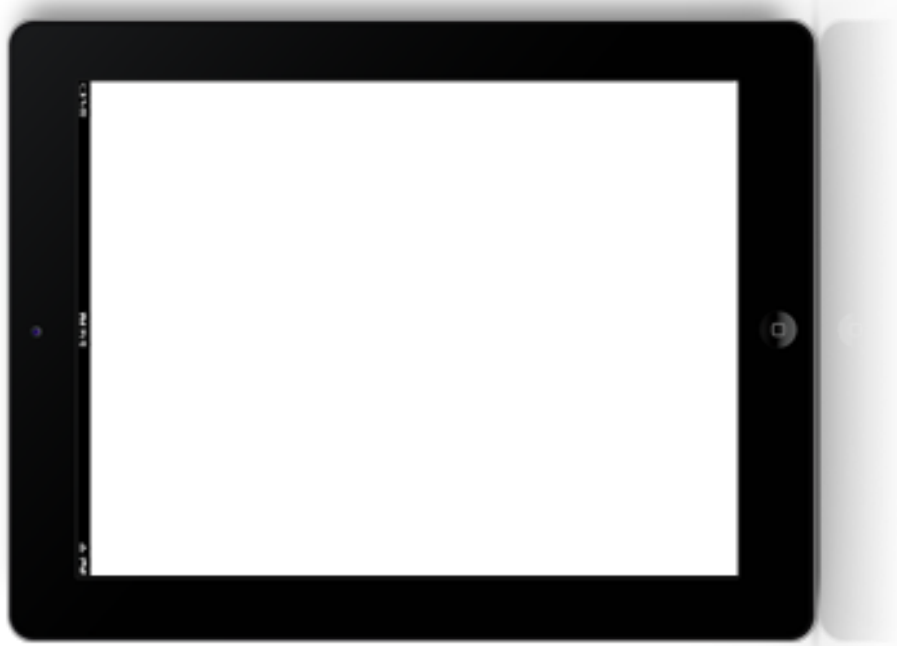
8.3 Design and development of products and services

8.4 Control of externally provided processes, products and services

8.1 Operational planning and control

The organization shall plan, implement and control

- the processes needed to meet the requirements for the provision of products and services, and
- to implement the actions determined in Clause 6 (Planning)



8.1 Operational planning and control

a) Requirements

determining the requirements

b) Criteria

establishing criteria

c) Resources

determining the resources needed

d) Controls

implementing control of the processes

e) Documentation

determining, maintaining and retaining documented information to the extent necessary

8.2 Requirements for products and services

- 8.2.1 Customer communication
- 8.2.2 Determining the requirements for products and services
- 8.2.3 Review of the requirements for products and services
- 8.2.4 Changes to requirements for products and services

8.2 Requirements for products and services

CUSTOMER COMMUNICATION

8.2.1 Customer communication

DETERMINE REQUIREMENTS

8.2.2 Determining the requirements for products and services

REVIEW REQUIREMENTS

8.2.3 Review of the requirements for products and services

CHANGES

8.2.4 Changes to requirements for products and services

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

8.2 Requirements for products and services

8.2.2 Determining the requirements for products and services

ORGANIZATIONAL

Requirements considered necessary by the organization

LEGAL

Applicable statutory and regulatory requirements

Organization can meet the claims

8.2 Requirements for products and services

8.2.3 Review of the requirements for products and services

8.3.2.1

- The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers.

- The organization shall conduct a review before committing to supply products and services to a customer

8.2 Requirements for products and services

8.2.3 Review of the requirements for products and services

CUSTOMER
specified by the customer

NECESSARY
not stated by the customer, but necessary

ORGANIZATION
specified by the organization

LEGAL
statutory and regulatory requirements

CHANGES
contract or order requirements differing from those previously expressed.

8.2 Requirements for products and services

8.2.3 Review of the requirements for products and services

- The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

- The customer’s requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

8.2 Requirements for products and services

8.2.3 Review of the requirements for products and services

8.2.3.2

The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

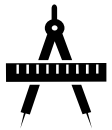
8.2 Requirements for products and services

8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed:

- ensure that relevant documented information is amended,
- relevant persons are made aware of the changed requirements,

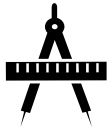
8.3 Design and development of products and services



- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes.

8.3 Design and development of products and services

8.3.1 General

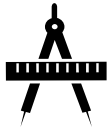


Establish, implement and maintain a design and development process -

- that is appropriate to ensure the subsequent provision of products and services.

8.3 Design and development of products and services

8.3.2 Design and development planning



In determining the stages and controls for design and development, consider:

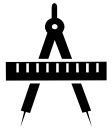
a) the nature, duration and complexity of the activities;

b) the required process stages, including applicable reviews;

c) the required verification and validation activities;

8.3 Design and development of products and services

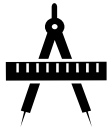
8.3.2 Design and development planning



- d) the responsibilities and authorities involved in the process;
- e) the internal and external resource needs
- f) the need to control interfaces between persons involved in the process;
- g) the need for involvement of customers and users in the process;

8.3 Design and development of products and services

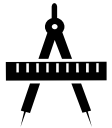
8.3.2 Design and development planning



- h) the requirements for subsequent provision of products and services;
- i) the level of control expected for process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate that design and development requirements have been met.

8.3 Design and development of products and services

8.3.3 Design and development inputs



Determine the requirements essential for the specific types of products and services to be designed and developed.

8.3 Design and development of products and services

8.3.3 Design and development inputs

Functional

functional and performance requirements

SIMILAR

information derived from previous similar design and development activities;

LEGAL

statutory and regulatory requirements

CODES

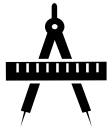
standards or codes of practice that the organization has committed

FAILURE

potential consequences of failure due to the nature of the Products/ Services

8.3 Design and development of products and services

8.3.3 Design and development inputs



- Inputs shall be adequate, complete and unambiguous
- Conflicting inputs shall be resolved
- Retain documented information on design and development inputs.

definition

REVIEW

determination of the suitability, adequacy or effectiveness of an object to achieve established objectives

definition

VERIFICATION

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

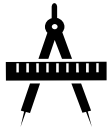
definition

VALIDATION

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

8.3 Design and development of products and services

8.3.4 Design and development controls



apply controls to ensure that:

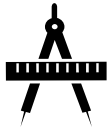
a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

8.3 Design and development of products and services

8.3.4 Design and development controls



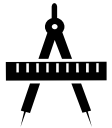
- d) validation activities to ensure that the resulting products and services meet the requirements for the specified application or intended use;

- e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

- f) documented information of these activities is retained.

8.3 Design and development of products and services

8.3.5 Design and development outputs

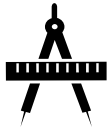


ensure that outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

8.3 Design and development of products and services

8.3.5 Design and development outputs

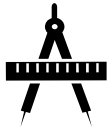


d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8.3 Design and development of products and services

8.3.6 Design and development changes

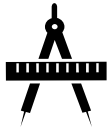


- identify, review and control changes made

  during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

8.3 Design and development of products and services

8.3.6 Design and development changes



Retain documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

- 8.4.1 General
- 8.4.2 Type and extent of control
- 8.4.3 Information for external providers

definition

EXTERNAL PROVIDER

provider that is not part of the organization

8.4 Control of externally provided processes, products and services

8.4.1 General

- ensure that externally provided processes, products and services conform to requirements.

8.4 Control of externally provided processes, products and services

8.4.1 General

determine the controls when:

- a) products and services are intended for incorporation into the organization's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the organization
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall determine and apply criteria for the

- evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

- The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4 Control of externally provided processes, products and services

8.4.2 Type and extent of control

- Ensure that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers.

8.4 Control of externally provided processes, products and services

8.4.2 Type and extent of control

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output

8.4 Control of externally provided processes, products and services

8.4.2 Type and extent of control

- c) take into consideration:
  1) the potential impact on the organization's ability to consistently meet requirements;
  2) the effectiveness of the controls applied by the external provider;

- d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4 Control of externally provided processes, products and services

8.4.3 Information for external providers

- ensure the adequacy of requirements prior to their communication to the external provider.

8.4 Control of externally provided processes, products and services

8.4.3 Information for external providers

Communicate requirements for:

- a) products/services to be provided;
- b) approvals
- c) competence
- d) interactions with the organization
- e) control and monitoring of performance
- f) verification or validation activities

8.5 Production and service provision

- 8.5.1 Control of production and service provision
- 8.5.2 Identification and traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation
- 8.5.5 Post-delivery activities
- 8.5.6 Control of changes

8.5 Production and service provision

8.5.1 Control of production and service provision

- The organization shall implement production and service provision under controlled conditions.

8.5 Production and service provision

8.5.1 Control of production and service provision

- Controlled conditions, as applicable:

a) documented information on:
   1) the characteristics
   2) the results to be achieved;

b) Availability of monitoring and measuring resources

c) implementation of monitoring and measurement activities

8.5 Production and service provision

8.5.1 Control of production and service provision

- d) infrastructure and environment
- e) competent persons
- f) validation, and revalidation, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) actions to prevent human error;
- h) release, delivery and post-delivery activities.

8.5 Production and service provision

8.5.2 Identification and traceability

- The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
- The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

8.5 Production and service provision

8.5.2 Identification and traceability

- The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

definition

TRACEABILITY

ability to trace the history, application or location of an object

8.5 Production and service provision
8.5.3 Property belonging to customers or external providers

- Exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

- Identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

8.5 Production and service provision
8.5.3 Property belonging to customers or external providers

- When the property of a customer or external provider is:

  - lost, damaged or otherwise found to be unsuitable for use,

  the organization shall :
  - report this to the customer or external provider and
  - retain documented information on what has occurred.

8.5 Production and service provision

8.5.4 Preservation

- The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5 Production and service provision

8.5.5 Post-delivery activities

- Meet requirements for post-delivery activities.

In determining the extent of post-delivery activities consider:

a) Legal requirements;
b) the potential undesired consequences
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

8.5 Production and service provision

8.5.6 Control of changes

- Review and control changes, to the extent necessary to ensure continuing conformity with requirements.

  Retain documented information describing the
  - results of the review of changes
  - the person(s) authorizing the change,
  - any necessary actions arising from the review.

8.6 Release of products and services

- The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

- The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

8.6 Release of products and services

The organization shall retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1

Ensure that outputs that do not conform to their requirements are:

- identified and
- controlled

to prevent

- their unintended use or
- delivery.

8.7 Control of nonconforming outputs

Take appropriate action based on:

- the nature of the nonconformity and
- its effect on the conformity of products and services.

This shall also apply to nonconforming products and services detected

- after delivery of products,
- during or after the provision of services.

8.7 Control of nonconforming outputs

- Ways to deal with nonconforming outputs

a) correction (Conformity to the requirements shall be verified)

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

8.7 Control of nonconforming outputs

8.7.2

Retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.